REMARKS

Claims 1-2, 4-5, 7-12, 14-21 are pending in the application. Of the pending claims, Claims 11 and 12 are withdrawn. Reconsideration of the present application is respectfully requested.

Priority

Applicant appreciates acknowledgment of the priority documents and requests that the Office Action Summary sheet be updated accordingly for the section entitled **Priority under 35 U.S.C. §119** and a copy returned to applicant.

Claim Interpretation

The Office Action states that Claims 18, 14 and 15 are interpreted as Markush claims. In the foregoing amendment, Claim 15 has been amended to eliminate the Markush claim language. Applicant submits that interpretation of Claim 15 as a Markush claim is no longer appropriate.

Claim Objections

Claim 16 has been objected to for incorrect spelling of peristalsis. In light of the amendment to Claim 16 that removes the word in question, it is respectfully requested that the objection to Claim 16 be withdrawn.

Claim Rejections - 35 USC §112

Claim 16 has been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In particular, the Examiner did not consider page 26, lines 8-14 as supporting the phrase in Claim 16 "peristalsis promoting agent." Claim 16 has been amended to include the phrase "swell through moisture in saliva or other moisture in the mouth of a patient to form a gel that changes into a form having a size, shape, elasticity,

viscosity so that swallowing is easy for the patient" as a replacement for the phrase "comprises a peristalsis promoting agent." As the specification for example at page 26, lines 8-14, clearly supports the language now found in Claim 16, it is respectfully requested that the rejection of Claim 16 under 35 U.S.C. §112, first paragraph be withdrawn.

Claims 4-5 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite because these claims depend from cancelled claim 3. Claim 4 has been amended to depend from Claim 1, therefore correcting the dependency of Claims 4-5. As Claims 4-5 now comply with the definiteness requirements of 35 U.S.C. §112, second paragraph, it is respectfully requested that the Examiner's rejection of Claims 4-5 under 35 U.S.C. §112, second paragraph be withdrawn.

Claim Rejections - 35 USC §103

Claims 1-2, 4-5, 7-10 and 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamura (Yamamura). This rejection is respectfully traversed for the following reasons.

Yamamura discloses a multi-layered film that is very different from the agent of the presently claimed orally administered agent. Yamamura discloses a triple-layered film consisting of an adhesive layer, a drug layer and a layer made difficult to dissolve in water (non-adhesive layer) (col. 2 lines 11-17). In some cases the adhesive layer is combined with the drug layer (col. 2 line 14). The purpose of the adhesive layer is steady application to mucous membrane in an oral cavity and should not to come off by movement of mucous membrane (cheek) and does not move easily by force of tongue (col. 14 lines 15-18). The adhesive layer of Yamamura should be powder (col. 3 lines 19-20). The layer is difficult to dissolve in water (non-adhesive layer) and secures the drug layer next to the mucous membrane, thereby preventing digestion since the drug layer does not dissolve in the mouth.

Applicant's claimed invention is different from Yamamura since it is an *orally administered agent* comprising two water-swellable gel-forming layers surrounding a drug layer that is easily swallowed and digested. Applicant's Claim 1 does not recite an adhesive element to a mucous membrane (biological body). The language in Claim 1 that reads "*free of a bioadhesive layer*" is the constituent feature of Claim 1. Applicant respectfully asserts that Yamamura does not teach applicant's claimed orally administered agent and that there is no reason for one skilled in the art to use the teachings of Yamamura for an orally administered agent as presently claimed.

Although some of the materials used in the teachings of Yamamura are water-soluble high molecular weight substances such as HPC, the present claims recite a *water-swellable gel-forming layers* [emphasis added] that also contain a film-forming agent to aid in making an easy to swallow agent. Therefore, as the water-swellable gel-forming layers of the presently claimed agent do not have the adhesion properties in the film of Yamamura, one skilled in the art would not remotely have reason to use the adhesion properties of Yamamura for *water-swellable gel-forming layers* for an orally administered agent as recited.

Further, the Examiner argues on page 8, lines 10-13 of the Office Action that:

> "Adhesive substance include carboxyvinyl polymer and its pharmaceutically acceptable non-toxic salts. These compound provided excellent adhesion when such a substance was applied on the drug containing layer (col. 5 lines 5-17)."

As described above, the goal of Yamamura is adhesion of the disclosed film preparation to the mucous membrane. The formulas and combination of chemicals in the Yamamura preparation are for that specific purpose. The presently claimed agent does not adhere to the mucous membrane, but rather provides two water-swellable gel-forming layers that swell through moisture in saliva or the like in the mouth of a patient to form a gel that changes into a

form having a size, shape, elasticity, viscosity so that swallowing is easy for the patient. One of ordinary skill in the art would have no reason to use the teachings of Yamamura to formulate a film that is easily swallowable. For the reasons given above, applicant respectfully submits that the teachings of Yamamura does not contemplate or suggest the inventions set forth in the present claims. *United States* v. *Adams,* 383 U.S. 39, 40 (1966); *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007).

The Office Action identifies on page 9, first paragraph the elements in the present application that are not included in the adhesive layer of Yamamura. As explained repeatedly by USPTO Board of Appeals and Interferences and elsewhere in the case law, a reference cannot be properly modified if the effect would be to destroy the invention on which the referenced patent is based. *Ex parte Hartmann*, 186 USPQ 366 (P.T.O.Bd.Ap. 1974); *Ex parte Thompson*, 184 USPQ 558 (P.T.O.Bd.Ap. 1974). See also *In re Rosen* 213 USPQ 347 (CCPA) 1982; and *In re Dembiczak,* 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). The elements that are absent in the teachings of Yamamura represent significant modifications that destroy the presently claimed agent as recited by Applicant.

The Examiner concludes on page 9, last paragraph of the Office Action that:

> "It would have been obvious to one of ordinary skill in the art to utilize carboxyvinyl polymer in both layers surround the drug containing layer. One of ordinary skill in the art would have been motivated to add this adhesive agent as it is taught by Yamamura et al. as providing excellent adhesion when applied to the drug-containing layer. By having the adhesive component in both layers, adhesion to the drug-containing layer can be achieved."

In the quote cited above, the Examiner has suggested that the ordinary artisan would have modified the layer made difficult to dissolve in water (non-adhesive layer). Applicant strongly disagrees that modification of this layer is obvious at all. Firstly, the adhesive layer and other

layers are made difficult to dissolve in water and are obviously intended to serve very different functions. This is further supported in that Yamamura does not teach the percentages and formulation comprising polyvinyl alcohol as admitted in the Office Action on page 9, first paragraph.

While in the presently claimed agent, the first and second layers may have a similar function, Yamamura clearly describes different functions for each layer. Also, it is unclear as to what would have motivated the ordinary artisan to have modified the non-adhesive layer at all, and particularly the modification suggestion by the Examiner, as such modification may disrupt the important functions these layers are intended to provide.

Further, the film adhesion disclosed in Yamamura is different from applicant's claimed invention. Applicant respectfully submits that the Examiner is making a conclusion about adhesion of the layers of the film to *each other* while the teachings of Yamamura use the term adhesion to refer to adhering the film to the mucous membrane. The ordinary artisan would have no reason to modify any compositions of the layers of the film of Yamamura because adhesion of the film of Yamamura to the mucous membrane would have been adversely affected if the layers were modified as suggested by the Examiner.

The preamble of the claims recites "an orally administered agent free of a bioadhesive layer." Yamamura contains a bioadhesive layer, the adhesive layer intended to adhere to a mucous membrane in the oral cavity. Contrarily, the presently claimed invention is directed to solving problems unique to an orally administered agent containing a drug. It is well established in the case law that if a limitation in the preamble of a claim necessarily gives meaning to the claim and properly defines the invention, then such limitation must be considered when determining the patentability of the claims. The predecessor court of the Court of Appeals for

the Federal Circuit (CAFC), namely, the Court of Custom and Patent Appeals (CCPA), summarized this approach in *Kropa v. Robie,* 88 USPQ 478(1951), after reviewing some 37 cases that turned on the limiting nature of the preambles to the claims in suit. See also *Loctite Corp v. Ultraseal Ltd.,* 228 USPQ 90, 94 (Fed. Cir. 1985). According to the court in Kropa:

> "[T]he preamble has been denied the effect of a limitation where ... the claim or [interference] count apart from the introductory clause completely defined the subject matter [of the invention], and the preamble merely stated a purpose or intended u se of that subject matter. On the other hand, in those... cases where the preamble to the claim our count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts."

Examples of preambles cited in *Kropa* as expressly or impliedly help to express a limitation in the claims are "An insecticide" and "An insecticide composition." Applicant respectfully submits that the claims in this application present precisely the situation where the preamble of a claim has been held to express a limitation in the claim in *Kropa*. The preamble of applicant's claims distinguishes the presently claimed invention by defining an orally administered agent free of a bioadhesive layer, which area of technology is unique and presents significantly more difficulties compared to, for example, the film applied to a mucous membrane, such as that proposed by Yamamura Therefore, Applicant respectfully submits that teachings that are not concerned with an orally administered agent free of a bioadhesive layer, such as that of Yamamura, could not possibly give reason to one of ordinary skill in the art to the presently claimed orally administered agent.

Based on the foregoing arguments, applicants submit that the present claimed agent is patently distinguishable from the teachings of Yamamura.

Claims 17-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Takayanagi et al . (Takayanagi), in view of Kuroya et al. (Kuroya) and Geoghegan et al. (Geoghegan). This rejection is respectfully traversed for the following reasons.

The present invention as recited in Claims 17-21 is drawn to an agent with multiple drug-containing layers that are heat-sealed via an intermediate layer which includes a heat-sealing adhesive. The agent has a water-swellable gel-forming layer as an outermost layer.

Takayanagi discloses adhesive medical tapes for oral mucosa, having a support layer composed of an intestine-soluble polymer, and a medicament-containing layer composed of a water-soluble polymer containing drug. The purpose of the support layer is to prevent the form of the adhesive medical tape from being collapsed or deformed (col. 3 lines 50-53). The Examiner has noted that the medicament layer is preferably composed of two or more layers. However, Takayanagi also describes at col. 4 lines 27-31 that "[i]n case to two medicaments layers a solution which is obtained by dissolving the components of the second medicament layer in the solvent is spread on the first medicament layer and dried to form a second medicament layer." Therefore, Takayanagi fails to teach or suggest two medicament-containing layers with an intermediate layer therebetween.

The Examiner has admitted that Takayanagi fails to disclose medicament layers comprising polyvinyl acetate. In order to cure the defects of Takayanagi, the Examiner has added the teachings of Kuroya and Geoghegan. Kuroya is also directed to a film intended for use in the oral cavity. Kuroya discloses a drug preparation having a film "excellent in shape retention on water absorption, and adhesive to the oral mucosa for an extended time" (col. 2, lines 28-30). However, Kuroya fails to disclose multiple medicament layers and does not disclose the presently claimed heat-sealing adhesive containing intermediate layer. Therefore,

the combined teachings of Kuroya and Takayanagi fail to disclose the presently claimed invention.

The teachings of Geoghegan are added as disclosing pharmaceutical formulations where after coating, the product is transferred to a tray drying oven for drying. The heating in the methods of Geoghegan is for *drying*, not for *heat-sealing* two layers to each other. Since the pharmaceutical formulation disclosed by Geoghegan is of a different form (a 24 hour controlled release table containing homogeneous spheres of drug) than the tape of Takayanagi or Kuroya, the ordinary artisan would have no reason to use the drying method of Geoghegan since the drying methods disclosed in Kuroya (col. 4 line 63-65) are more applicable to an adhesive tape type medicament.

The Examiner concludes that combining the teachings of Takayanagi with Kuroya and Geoghegan provides a film with better shape retention and long-term use in the oral cavity, and that it would have been obvious to utilize a drying oven to dry the resulting film. Applicant strongly disagrees for the following reasons. The presently claimed orally administered agent is free of a bioadhesive layer. Therefore the film of the present invention does not adhere to a mucous membrane as would the films of Takayanagi, Kuroya and Geoghegan. Further, one skilled in the art would have no reason to combine the references to obtain a multilayer film heat-sealed to each other via an intermediate layer that includes a heat-sealing adhesive as recited in Claims 17-21. The cited references, taken alone or together, fail to disclose either an intermediate layer between multiple drug layers or an intermediate layer including a heat-sealing adhesive therein.

To clarify, Takayanagi and Kuroya use the term adhere to discuss the relationship between the medicament containing tape and a mucous membrane. Adhesion is desired between

the medical tape and the mucous membrane. This teaches away from the present invention where the outermost layer is a water-swellable gel-forming layer that, upon introduction of moisture as saliva or the like in the mouth of a patient to form a gel that changes into a form having a size, shape, elasticity, viscosity so that swallowing is easy for the patient. Adherence to mucosa is not desired. The presently claimed invention uses the term adhere to refer to layers of the agent to other layers, as in the multiple drug-containing layers are adhered to each other via a heat-sealing adhesive found in an intermediate layer between the drug-containing layers.

The claimed invention, wherein "the multiple drug-containing layers are heat-sealed via an intermediate layer which includes a heat-sealing adhesive" is distinguishable from the medical adhesive tape of Takayanagi, even taken in combination with Kuroya and Geoghegan, which teaches drying a first medicament layer on top of another. Firstly, the claims recite an intermediate layer between the drug layers. Secondly, drying one layer on top of another, either through air or oven drying, is a different process from heat sealing with a heat-sealing adhesive.

Further, as discussed above, the preamble of the present claims recites "an orally administered agent free of a bioadhesive layer." Takayanagi contains a bioadhesive layer, the adhesive layer intended to adhere to a mucous membrane in the oral cavity. Contrarily, the presently claimed invention is directed to solving problems unique to an orally administered agent containing a drug. As argued previously, it is well established in the case law that if a limitation in the preamble of a claim necessarily gives meaning to the claim and properly defines the invention, then such limitation must be considered when determining the patentability of the claims. The preamble of applicant's claims distinguishes the presently claimed invention by defining an orally administered agent free of a bioadhesive layer, which area of technology is unique and presents significantly more difficulties compared to, for example, the film applied to a mucous membrane, such as proposed by Takayanagi, Kuroya and Geoghegan. Therefore,

Applicant respectfully submits that the teachings of Takayanagi, Kuroya and Geoghegan, alone or in combination, are not concerned with an orally administered agent free of a bioadhesive layer and an artisan would have no reason based thereon to contemplate the presently claimed invention.

Applicant respectfully submits that the combination of Takayanagi, Kuroya and Geoghegan teaches away from the presently claimed invention and therefore cannot contemplate or suggest the inventions set forth in the present claims. If one did combine the teachings of Takayanagi, Kuroya and Geoghegan, the ordinary artisan would have obtained an adhesive medical tape with medicament layers as taught by Takayanagi comprising polyvinyl acetate as taught by Kuroya and dried in an oven at 50°C as taught by Geoghegan. This combination of references still discloses at best a modified adhesive medical tape. Takayanagi, Kuroya and Geoghegan teach away from formulating a film that is easily swallowable because the intended use of the tape is adherence to a membrane in the oral cavity. Takayanagi, Kuroya and Geoghegan also teach away from a multilayer medicament containing an intermediate layer between the drug-containing layers because the reference discloses placing one layer directly upon another and drying and no teaching suggestion or motivation is provided in Takayanagi, Kuroya or Geoghegan for altering this drug layering pattern. *United States* v. *Adams*, 383 U.S. 39, 40 (1966); *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ2d 1385, 1396 (2007).

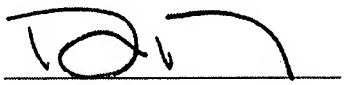
Claims 1-2, 4-5, 7-10, 14-16 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/540,952. Claims 17-21 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 10/592,953.

Appropriate terminal disclaimers will be filed upon notification that claims 1-2, 4-5, 7-10, 14-16, 17-21 have been allowed.

In view of the foregoing, applicants respectfully submits that this application is in condition for allowance. A timely notice to that effect is respectfully requested.

Please charge any unforeseen fees that may be due to Deposit Account No. 50-1147.

Respectfully submitted,



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